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5. 510(k) Summary

AUG 30 2007

Submitted by:
Organogenesis, Inc.
150 Dan Road
Canton, MA 02021

Contact:
Patrick R. Bilbo
Telephone: 781-401-1155
Facsimile: 781-401-1288

Date: June 6, 2007

Device:

Trade Name:	FortaGen® Oral Membrane
Common/Usual Name:	Resorbable dental barrier membrane, animal source
Classification Name:	Not applicable
Regulatory Class:	Not classified

Predicate Devices:
The device is similar to predicate collagen-based surgical mesh devices and collagen dental membranes previously cleared for commercial distribution. The relevant predicate devices include FortaGen Surgical Mesh (K021105), formerly FortaFlex Surgical Mesh, manufactured by Organogenesis Inc., Ossix-Plus (K053260) manufactured by Colbar LifeScience, Ltd., and Bio-Gide Resorbable Bilayer Membrane (K050446) manufactured by Ed. Geistlich Soehne Ag für Chemische Industrie.

Intended Use:
FortaGen Oral Membrane is intended to be used during guided bone regeneration (GBR) and guided tissue regeneration (GTR) procedures as a biodegradable barrier membrane for:

- Ridge augmentation for later implant insertions;
- Simultaneous ridge augmentation and implant insertions;
- Ridge augmentation around implants inserted in delayed extraction sites;
- Ridge augmentation around implants inserted in immediate extraction sites;
- Alveolar ridge preservation consequent to tooth (teeth) extraction(s);
- Over the window in lateral window sinus elevation procedures;
- In implants with vertical bone loss due to infection, only in cases where satisfactory debridement and implant surface disinfection can be achieved;
- In intra bony defects around teeth;

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- For treatment of recession defects, together with coronally positioned flap;
- In furcation defects in multi-rooted teeth.

Device Description:

FortaGen Oral Membrane consists of a multi-laminate sheet predominantly of Type I porcine collagen. The device is supplied hydrated in sheet form in sizes ranging from 13 mm x 25 mm to 40 mm x 50 mm in sterile double layer peelable packaging.

Technological Characteristics and Performance Data:

The FortaGen Oral Membrane, like its predicate devices, is manufactured from porcine collagen and is designed to resorb within six months. FortaGen Oral Membrane has been shown to be biocompatible. Its handling characteristics and resorption profile are substantially equivalent to those of its predicate devices, and the FortaGen Oral Membrane should function equivalently to Ossix-Plus and Bio-Gide when used as intended for GTR and GBR procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2008

Mr. Patrick R. Bilbo
Vice President, Regulatory and Clinical Affairs
Organogenesis, Incorporated
150 Dan Road
Canton, Massachusetts 02021

Re: K071555
Trade/Device Name: FortaGen Oral Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: August 17, 2007
Received: August 20, 2007

Dear Mr. Bilbo:

This letter corrects our substantially equivalent letter of August 30, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name: FortaGen Oral Membrane

Indications for Use:

FortaGen Oral Membrane is intended to be used during guided bone and guided tissue regeneration procedures as a biodegradable barrier membrane for:

- Ridge augmentation for later implant insertions;
- Simultaneous ridge augmentation and implant insertions;
- Ridge augmentation around implants inserted in delayed extraction sites;
- Ridge augmentation around implants inserted in immediate extraction sites;
- Alveolar ridge preservation consequent to tooth (teeth) extraction(s);
- Over the window in lateral window sinus elevation procedures;
- In implants with vertical bone loss due to infection, only in cases where satisfactory debridement and implant surface disinfection can be achieved;
- In intra bony defects around teeth;
- For treatment of recession defects, together with coronally positioned flap;
- In furcation defects in multi-rooted teeth.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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